

REMARKS

Claims 51-55, 58-85, and 88-92 currently appear in this application. The Office Action of November 26, 2004, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 112

Claims 83, 84 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the preparation of claim 50 is now a dry powder form, while claim 83, dependent therefrom, refers to the composition as a dry powder.

This rejection is respectfully traversed. Claim 50 has been replaced by new claim 90. Claim 90 recites in step (b) that the solution is freeze-dried to form a dry powder, as required by claim 83. Claims 84 and 85 have been cancelled as being redundant in view of new claim 90.

Art Rejections

Claims 61, 63-78 and 80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Stahl.

This rejection is respectfully traversed. Claim 50 has been replaced by claim 90, which claim requires that the liposomes be prepared using a freeze-drying (lyophilization) step. This freeze-drying step, step (b), produces liposomes which produces unexpectedly superior liposomes s compared to liposomes prepared by conventional methods. The declaration of Yেকেzkel Barenholz, submitted herewith, describes preparation of liposomes in which the liposomes in step (b) were dried by drying in air at room temperature, evaporation under nitrogen at room temperature, or by lyophilization. This declaration demonstrates that lyophilization produces unexpectedly superior liposomes. Since Stahl et al. do not lyophilize the liposomes prepared, but rather evaporate the solvent with nitrogen, there can be no finding of anticipation.

It should also be noted that Stahl et al. consider carotenoids such as lycopene, alpha-tocopherol, alpha-carotene, beta-cryptxanthin, zeaxanthin, beta-carotene and lutein all to have antioxidant activity, and that all of these carotenoids can be used to form liposomes.

Claims 50-55, 58-62, 65-78, 80, 82-85 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al.

This rejection is respectfully traversed. As noted above, the declaration of Professor Barenholz clearly demonstrates that liposomes prepared by freeze-drying the formed liposomes produces unexpectedly superior results to merely drying the liposomes in nitrogen, as disclosed by Stahl et al.

Claims 50-55, 58-85 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maybeck in view of Stahl et al.

This rejection is respectfully traversed. Maybeck et al. dissolve the phospholipid and the carotenoid in an organic solvent and remove the solvent to prepare a dry preparation, whereas the instant application first dissolves the lipid in the organic solvent and then carotenoid is added to the solution. In the present invention, it is essential that first the liposome-forming lipid be dissolved in an organic solvent (close to saturation), and only then is the carotenoid added.

The order of action of components is critical in obtaining stable formulations. Table 6B of the instant specification, page 28, shows that formulations prepared according to the method of the sent invention, i.e., first dissolving the lipid and only then dissolving the lycopene, results in a formulation that is more stable as compared to

those prepared by first dissolving the carotenoid and only then adding the lipid.

Claims 50-55, 58-85 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Stahl et al.

This rejection is respectfully traversed. Smith dries liposomes by rotary evaporation under vacuum. It is clear from the Barenholz declaration that only lyophilization produces liposomes that have unexpectedly superior properties. The claims have now been amended to recite that the liposomes are lyophilized. Therefore, Smith adds nothing to the disclosures of Stahl et al. and Maybeck et al. to render the present claims obvious.

Claims 50-55, 58-85 and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Stahl et al.

This rejection is respectfully traversed. Neither of the cited references discloses or even suggests that the order of addition of lipid and carotenoid is critical, nor that that liposomes so formed are lyophilized to remove solvent. The present claims require both that the phospholipid be dissolved prior to addition of the carotenoid.

Appln. No. 10/073,365
Amd. dated February 25, 2005
Reply to Office Action of November 26, 2004

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maybeck or Stahl, cited above, further in view of Mackaness.

This rejection is respectfully traversed. Although Mackaness discloses that organic solvents such as cyclohexane or chloroform can be used to dissolve phospholipids in preparing liposomes, Mackaness does not supply any suggestion or disclosure to add the phospholipid to the solvent prior to adding the carotenoid, nor that the liposomes so produced must be dried by freeze-drying or lyophilization.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 

Anne M. Kornbau
Registration No. 25,884

AMK:srd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\C\cohn\Barenholz8a\Pto\AMD 25 FEB 05.doc